RESPONSE TO RESTRICTION REQUIREMENT

Serial Number: 10/735,289

Filing Date: December 12, 2003

Title: USE OF PROEPITHELIN TO PROMOTE WOUND REPAIR AND REDUCE INFLAMMATION

REMARKS

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In the Restriction Requirement mailed September 6, 2006, the Examiner has restricted the claims under 35 U.S.C. § 121 into twenty (20) different groups. Applicant elects, with traverse, Group I, claims 1-46, drawn, in part, to a method of administering to a mammal a proepithelin (PEPI), alone or with secretory leukocyte protease inhibitor (SLPI), wherein the PEP1 comprises SEQ ID NO:1 and the SLPI comprises SEQ ID NO:7.

The Restriction Requirement is traversed on the basis that Restriction Requirements are optional in all cases (M.P.E.P. § 803). If the search and examination of an entire application can be made without serious burden, the Examiner must examine the application on the merits, even though it includes claims to distinct or independent inventions. M.P.E.P. § 803. As explained in more detail below, Applicant submits that a search of at least several of the groups would not be so burdensome that the Examiner could not easily search them together.

Applicants also respectfully traverse the restriction into twenty different groups based largely on minor sequence differences between proepithelin (PEPI) and secretory leukocyte protease inhibitor (SLPI). Restriction into such a large number of groups essentially makes each species of proepithelin (PEPI) and secretory leukocyte protease inhibitor (SLPI) a separate invention. As provided by the MPEP, species may be related inventions and need not be subject to restriction. See MPEP § 806.04(b). In particular, where species are claimed under a common genus and are related, the question of restriction is determined by the practice applicable to election of species and the practice applicable to other types of restrictions. See id. Applicants also respectfully remind the Examiner that they are entitled to examination of a reasonable number of species, and that election of species is for the convenience of the Examiner in initiating the search.

Here, each of the species of PEPI and SLPI sequences are part of a single generic claim (e.g. claims 1 and/or 2). These generic claims explicitly define how the claimed species are related (types of PEPI and SLPI). The Examiner is reminded that M.P.E.P. § 803.02 states that "if the members of the Markush group are <u>sufficiently few in number</u> or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all the members of the Markush group in the claim on the merits, even though they

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are directed to independent and distinct inventions. In such a case, the Examiner will not . . . require restriction. [S]hould no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended . . . to the extent necessary to determine patentability of the Markush-type claim." (Emphasis added.)

Here, for example, the only difference between the subject matter of Groups I and II is that the PEPI has SEQ ID NO:2 in Group II, which is identical to the PEPI with SEQ ID NO:1 in Group I except for a single amino acid difference at position 454 (Gly in SEQ ID NO:1; Gln in SEQ ID NO:2). Thus, the subject matter of Groups I and II can readily be understood and examined together and there is little or no additional burden upon the Patent Office in a search and examination of these two species of PEPI together.

Applicant requests reconsideration of the restriction requirement, which is essentially a restriction to one species PEPI and one species of SLPI. If this request is denied, Applicant submits that additional species should be considered as required under M.P.E.P. § 803.02, if a prior art search of the elected species turns up no relevant prior art.

If the restriction requirement is maintained, Applicant requests rejoinder if a generic claim is allowed and reserves the right to reintroduce the claims in one or more Divisional or Continuation applications at a later date.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (516) 795-6820 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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